

Listing of Claims:

This listing of claims will replace all prior versions and listings of claims in the application:

1. (Currently Amended) A stable topical nanoparticulate spironolactone formulation comprising
nanoparticles having a mean diameter, measured by photon correlation spectroscopy, in the range of from about 300 nm to about 900 nm,
incorporated into a crystalline network system comprising a dispersion of solid crystals of polar lipids,
said lipids exposing their hydrophilic side outwards and their hydrophobic side inwards toward the spironolactone nanoparticles.
2. (Previously Presented) The formulation according to claim 1, comprising nanoparticles having a mean diameter, measured by photon correlation spectroscopy, in the range of from about 400 nm to about 600 nm
3. (Previously Presented) The formulation according to claim 1, wherein the lipid has a crystallization temperature of between 20°C and 100°C.
4. (Previously Presented) The formulation according to claim 1, wherein the lipid crystals are β crystals of a monoglyceride of a fatty acid having 12-18 carbon atoms, or ascorbic, phosphate or lactic esters of fatty acids or of monoglycerol ethers, or mixtures thereof.
5. (Previously Presented) The formulation according to claim 4, wherein the monoglyceride is 1-monolaurin, 1-monomyristin, 1-monopalmitin, or 1-monostearin, or a mixture of two or more thereof.
6. (Previously Presented) The formulation according to claim 1, wherein crystalline network structures of polar lipids are formed within a polar liquid.
7. (Previously Presented) The formulation according to claim 6, wherein the polar liquid is selected from water, glycerol, ethylene glycol, propylene glycol, or mixtures thereof.

8. (Previously Presented) A method of treating one or more of acne, hirsutism, androgenic alopecia, or rosacea, comprising topically applying to a subject in need thereof the nanoparticulate spironolactone formulation according to claim 1.
9. (Previously Presented) The formulation according to claim 1, wherein active drug is incorporated in the form of a nanosuspension.
10. (Previously Presented) The formulation according to claim 9, wherein the nanosuspension is an aqueous nanosuspension.
11. (Previously Presented) The formulation according to claim 10, wherein the nanosuspension comprises a stabilizer.
12. (Previously Presented) The formulation according to claim 11, wherein the stabilizer is sodium docusate.

Claims 13-14. (Canceled)

15. (Previously Presented) The method according to claim 22, wherein the spironolactone nanosuspension is topically applied.
16. (Previously Presented) The method according to claim 22, wherein the nanoparticles are incorporated into a cream base.
17. (Previously Presented) The method according to claim 16, wherein the cream base comprises a crystalline network of monoglycerides in water or other polar liquids.
18. (Currently Amended) A method of treating a condition that responds to anti-androgens comprising: administering a stable nanoparticulate spironolactone formulation according to claim 1 to a patient in need of such treatment, wherein said condition is acne, hirsutism, androgenic alopecia, or rosacea.
19. (Previously Presented) The method according to claim 18, wherein said condition is selected from the group consisting of acne, hirsutism, androgenic alopecia and rosacea.

Claim 20 (Cancelled)

21. (Previously Presented) A process for the preparation of a stable topical nanoparticulate spironolactone formulation comprising nanoparticles having a mean diameter in the range of from about 300 nm to about 900 nm as measured by photon correlation spectroscopy, said process comprising: incorporating a nanosuspension of spironolactone into an aqueous dispersion of solid crystals of polar lipids, said lipids having their hydrophilic side exposed outwards and their hydrophobic side inwards toward the spironolactone nanoparticles.
22. (Currently Amended) A method of treating a condition that responds to anti-androgens, comprising:
administering a stable spironolactone nanosuspension comprising nanoparticles having a mean diameter in the range of from about 300 nm to about 900 nm, as measured by photon correlation spectroscopy, in an amount effective to treat the condition, wherein said condition is acne, hirsutism, androgenic alopecia, or rosacea.
23. (Previously Presented) The method according to claim 8, wherein spironolactone active drug is incorporated into the formulation in the form of a nanosuspension.
24. (Previously Presented) The method according to claim 18, wherein spironolactone active drug is incorporated into the formulation in the form of a nanosuspension.
25. (New) The formulation according to claim 1, wherein said nanoparticles do not grow following seven months in storage at room temperature.
26. (New) The method according to claim 21, wherein said nanoparticles do not grow following seven months in storage at room temperature.
27. (New) The method according to claim 22, wherein said nanoparticles do not grow following seven months in storage at room temperature.